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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,616	12/01/2000	Arlindo L. Castelhana	1919/60390-G/JPW/GJG/CMR	5191
7590 01/27/2005				
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036		EXAMINER MCINTOSH III, TRAVISS C		
		ART UNIT PAPER NUMBER 1623		
DATE MAILED: 01/27/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,616

Applicant(s)

CASTELHANO ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-102,110,114-124,128-131 and 133-135 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 76-98 and 133-135 is/are allowed.
- 6) ☒ Claim(s) 99,117 and 118 is/are rejected.
- 7) ☒ Claim(s) 100-102,110,114-116,119-124 and 128-131 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed November 1, 2004 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 103-109 have been canceled.

Remarks drawn to rejections of Office Action mailed July 28, 2004 include:

Double Patenting Rejections: which have been overcome in part by applicant's amendment and have been withdrawn in part.

112 1st paragraph rejection: which has been overcome by applicant's amendments and have been withdrawn.

112 2nd paragraph rejections: have been maintained for reasons of record.

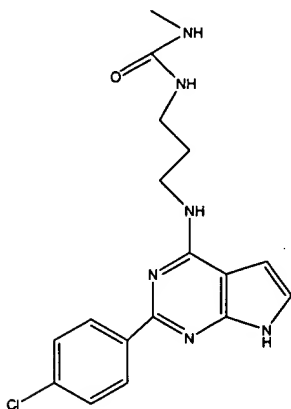
An action on the merits of claims 76-102, 110, 114-124, 128-131, and 133-135 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Double Patenting

The rejection of claim 99 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, and 4-6 U.S. Patent No. 6,686,366 is maintained for reasons of record. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the Markush groups of both claim sets comprise a compound of the same structure. Claim 99 comprises a compound having the following structure:



Claims 1 and 4-6 of the '366 patent claim the identical compound wherein the variables of '366 are defined as: $m=1$ (in claim 6); R_1 (of claim 6) is aminomethyl; R_3 is substituted aryl (chlorine substituted on benzene); and R_5 and R_6 are H.

Applicant's arguments filed November 1, 2004 have been fully considered but they are not persuasive. Applicants argue that the compounds of the instant application are improvements of the previously filed application, and thus are patentable over the prior art Markush group. Applicants additionally argue that it is unexpected that from the genus of compounds in the '366 patent that one could select one specific compound, like the compound as claimed in claim 99. However, as set forth earlier, the '366 patent encompasses the identical compound as set forth in claim 99 of the instant application. One of skill in the art would have found it obvious to select any of the compounds of the genus of the '366 patent and use it as an adenosine A3 agonist, as the '366 patent discloses the use of the claimed compounds in various methods of use (see claims 30-40). Moreover, arguments that the instantly claimed compounds are "later filed

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improvements” are not sufficient to overcome the instant rejection, as the compound as claimed in claim 99 is included in the genus of the ‘366 patent.

Claim Rejections - 35 USC § 112

The rejection of claims 117 and 118 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, is maintained for reasons of record. See MPEP § 2172.01. The omitted elements are: the actual condition which is being treated. The claim is drawn to treating “diseases associated with an A3 adenosine receptor” which is “associated with mast cell degradation”. The examiner is unclear as to exactly what is intended to be treated in the instantly set forth claim. Applicants argue that “it is known in the art that the A3 adenosine receptor has been *implicated* in mast cell degranulation”. The examiner notes that because something has been *implicated* as doing something, does not necessarily indicate it is directly related. Applicants additionally note that the additional limitation of requiring the diseases associated with mast cell degranulation added to the claim would unnecessarily limit the claim. Moreover, applicants note that the various disease states represented as those “associated with mast cell degranulation” are set forth in the specification on pages 13-16. However, the examiner notes that while there are various diseases discussed in pages 13-16 of the specification, the examiner finds nothing there about those which are associated with mast cell degranulation. In the absence of the identity of the actual diseases which are to be treated, the examiner is unclear of exactly what is to be treated.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

Allowable Subject Matter

Claims 76-98 and 133-135 are allowed.

Claims 100-102, 110, 114-116, 119-124, and 128-131 would be allowed if they were amended so they no longer depend from claim 99.

The prior art of record does not teach or fairly suggest the N-6 substituted 7-deazapurine compounds as set forth in claims 76-98, nor the methods of making or the methods of using the same. Nothing in the art of record is seen to motivate the skilled artisan to modify the 7-deazapurine as applicants have done.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

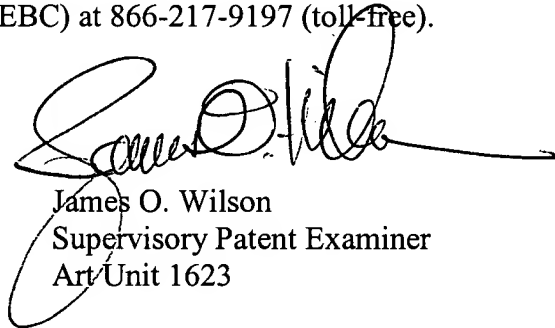
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
January 21, 2005



James O. Wilson
Supervisory Patent Examiner
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